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The authorship of research results and scientific publications in medical sciences

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Introduction. The article aims to present the rules for determining the authorship of research results and scientific publications under intellectual property law and the applicable standards.

Materials and methods. The study is based on copyright law, national and international codes of ethical conduct in research and scientific publications, including the European Code of Conduct for Research Integrity and the guidelines for publication in medical journals of the International Committee of Medical Journal Editors.

Results and discussion. The standards for the attribution of authorship to scientific results under intellectual property law, the applicable guidelines and customs are not consistent. Strict rules for determining the status of an author based on their creative contribution within the meaning of copyright law do not correspond in full extent to the needs of the sciences, where almost every contribution to research, clinical trials, and the preparation of publications is appreciated. In practice, this may create conflicting situations as to the proper identification and indication of authorship and co-authors.

Conclusions. Among the standards for recognizing authorship, copyright standards prevail. A compromise solution between the restrictive approach for attributing authorship (co-authorship) of works under copyright and the non-binding recommendation of the ethical codes, is to distinguish between the 'authors' and other 'non-authors' who contributed to the creation of work, thereby protecting the interests of all parties involved.

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Introduction

Although medicine and the healthcare system are increasingly subject to the standards of various areas of law (e.g. medical, pharmaceutical, personal data protection regulations), intellectual property law does not seem to be particularly relevant to these areas. This conclusion is not entirely appropriate. Firstly, patents and know-how are an essential tool for the protection of medicinal products, devices and methods for medical treatment. Secondly, publications containing the results of research work, or clinical trials in various fields of medicine are subject to copyright protection. This justifies even brief commentary on some problems in this field of law, even in medical journals.

Among the issues selected from the field of intellectual property covered by the series of articles "Intellectual Property Rights and Medicine", the problem of authorship and co-authorship of research results and publications is of importance in the field of research in medical science. Against this background, controversies and possible conflicts derive from a number of sources. First of all, there is the different understanding of creativity and authorship in sciences, and this based on intellectual property law. Secondly, various standards are provided under intellectual property law and the applicable national, international codes of ethics for research and scientific activities, as well as publication guidelines and recognized customs for attributing authorship.

Materials and methods

Determining guidelines for authorship (or co-authorship) and situations in which infringement of intellectual property rights

concerning authorship occur, requires the identification of the legal grounds appropriate for further analysis. It includes brief comments of what constitutes the subject of protection under intellectual property law and, consequently, who enjoys the moral right to the authorship of such intellectual creations.

Intellectual creativity and authorship, which have significant scientific, social and financial consequences, are immaterial goods protected as the personal rights of a natural person under the provisions of the Civil Code and as copyright rights by the Act on Copyright and Related Rights of 1994 [1].

The object of copyright is any manifestation of creative activity of an individual nature, established in any form, irrespective of its value, purpose or form of expression (work). In the field of research and scientific creations, these can be scientific articles, medical opinions, conference speeches, presentations, posters, databases. The possibility of qualifying an intellectual creation as a copyright work derives from the individual mode of expression of that work. The individual and original character of the work is understood as non-standard, unconventional, not resulting from predetermined requirements, but not its substantive, scientific, economic value, which are essential criteria of creativity relevant to the sciences. Copyright protection starts from the moment of expression of the work in any form (e.g. the oral communication of a conference presentation, an article saved in a computer memory). It also applies to unfinished works, fragments of works (e.g. an abstract of an article, a draft version of a scientific paper).

The criteria used for the assessment of the individual character of a work are liberal, and sometimes even trivial manifestations of intellectual creativity enjoy copyright protection. Meanwhile, copyright law discriminates against creativity in the area of the sciences, where the critical intellectual value is attributed to discoveries, new methods, pure research results, rather than the form and manner of their presentation or expression [2]. These creations 'as such', even when of significant scientific or practical importance, are explicitly excluded from protection by copyright law. According to Article 2^1 of the Polish Copyright Act, protection may apply to the form of expression only and no protection shall be granted to discoveries, ideas, procedures, methods and principles of operation as well as mathematical concepts.

This means that even a short, written description of, for example, the symptoms of cancer can be copyright protected. At the same time, breakthrough research results of a cancer treatment expressed in the form of numerical parameters or an innovative method of a cancer treatment won't enjoy copyright protection. Excluding such results from the protection of exclusive rights under intellectual property law presupposes that the creation of a monopoly on them would restrict freedom of research, access to results and technological progress [3].

The right to authorship of a work and signing it with one's name is one of the author's moral rights that should be distinguished from the economic rights giving the author (or the entity which acquired copyright) the exclusive right to exploit the work. Contrary to these copyright economic rights, which may be contractually transferred to another party, the moral right to authorship cannot be transferred or renounced. Another person or institution (e.g. a publisher) may be only authorized to exercise this right, for example by not signing the work with the author's name or using a special form of indicating the authorship.

The right to authorship of a work is vested in the author (an individual) who created the work. Authorship can be attributed to one or more persons (co-authors). Unfortunately, there is no binding definition of a "co-author", which leads to many disputes over co-authorship. Copyright law takes a restrictive approach to who can be a co-author. To be recognized as a co-author, a person must make "a creative contribution" to the creation of a work. For example, co-authors of a scientific article within the meaning of copyright law will be persons who "physically" prepared (wrote) such a paper, created its plan, layout, decided on a specific argumentation, formulated conclusions. In contrast, persons whose contribution to the common understanding is also significant are not considered authors in the sense of intellectual property law. For example, authors of the concept of the publication itself, the persons who have conducted research, obtained results, have been consultants, have made a substantive assessment or editorial corrections, have managed the research work or the project which resulted in its publication).

Copyright law does not "value" the authorship of a work in any way, i.e. there are no rules regarding placing the names of authors in any particular order (e.g. the leader of the research team as the first-mentioned author, other authors, etc.). The amount of creative contribution reflects shares in economic copyright rights to the work.

Authorship is a matter of fact: i.e. it results only from the point of creating a work or making a creative contribution within the meaning of copyright law. On the one hand, indicating someone as the author of a work (e.g. a publication), or including them in an agreement concerning the exploitation of the work (e.g. a publishing agreement), does not make such a person an "author" within the meaning of copyright law. On the other hand, given that copyright protection arises without any formalities (so that sometimes it may be challenging to prove being the author of a work) copyright law provides the so-called presumption of authorship. It considers as the author (co-author) a person whose name appears on a copy of the work (e.g. a hard copy of the manuscript) or whose name is communicated to the public in connection with the dissemination of the work (e.g. is mentioned at a conference as the presenter of a lecture). The presumption of authorship is advantageous in the case of a dispute on copyright infringement. Until a third party proves the person indicated as the author has not factually created the work, everybody must consider

the person stated on the work as being its author. Therefore, it is essential to remember to sign works with one's own name, and also indicate the fact when verbal communication of copyright works to the public takes place.

In addition to copyright standards, the proper indication of the authors of research results and scientific publications is the subject of various non-binding recommendations and codes of ethics, which introduce different rules on authorship than those indicated above.

Liberal standards in this respect are provided, for example, by the European Code of Conduct for Research Integrity [4]. The Code includes the possibility of attributing authorship and indicating the order of the author according to the assumption that the status of an author results from their significant participation in the planning of research, the collection of data or their interpretation. This ethical code also introduces a requirement for publishers and reviewers of publications to respect authorship in obtaining authors' consent to use their ideas, data, research results or the further interpretation of them.

At the national level, one example is the Code of Ethics for Researchers developed by the Commission on Ethics in Science [5]. It has been adopted by the General Assembly of the Polish Academy of Sciences in 2016 and is also used by many institutions in the field of medical science (e.g. medical universities, the Medical Centre for Postgraduate Education). In terms of copyright and publishing practices, this Code contains recommendations that the authorship of a scientific publication should be based solely on a creative and substantial contribution to the research. However, it defines the relevant contribution differently from copyright law, namely as a contribution consisting of significant participation in initiating a scientific idea, creating a concept and design, research, substantial involvement in data acquisition, analysis and interpretation of the results obtained, as well as a significant contribution to the drafting and writing of an article or the critical improvement of it in terms of intellectual content. The Code of ethics recognizes plagiarism as one of the forms of the offensive violation of ethical principles in science. It defines this broadly as an action consisting of the appropriation of someone else's ideas, research results or statements without correctly stating the source. Even though according to the Code it constitutes a violation of intellectual property rights, such a definition does not correspond to the understanding of plagiarism under copyright law, which can only be committed with regards to content which is protected by copyright. Since copyright does not protect the ideas or results themselves, but only the form the author uses to describe them, using somebody's else's results is not plagiarism in the legal sense, but can still be questioned as an infringement of the personal right to scientific creativity.

Autonomous recommendations for determining who is an the author, directly related to publications in medical journals, include the recent recommendations of the International Committee of Medical Journal Editors, called the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals of 2019 [6]. These recommendations recognize the author of a publication as a person who meets the following conditions cumulatively:

1. has made a significant contribution to the concept or design of the paper, obtaining, analyzing or interpreting the data covered by the work;
2. elaborated and critically explained the relevant content;
3. has approved the final version of the work;
4. was responsible for the correctness and accuracy of the presented content.

Consequently, persons who do not meet all the conditions indicated should not be reported as authors. The conditions defined in this way are not consistent with the requirements of copyright law, where for the recognition of authorship, the activities mentioned in point 2 and 3 are relevant and sufficient. According to the recommendations it is appropriate to indicate persons who performed auxiliary functions in the preparation of the work (e.g. performed general supervision over the research group, participated in the editing of the work and linguistic correction), but as a category separate from the authors (e.g. as "participating researchers").

Results and discussion

Copyright law protects the form of expression and surprisingly not the substantive, scientific or applicable content. Thus, the intellectual property system does not meet the needs of the sciences, where the persons responsible for discoveries, those developing scientific methods, generating valuable experimental data are traditionally also considered authors. Confusions regarding authorship even deviate from the conviction that the author is someone whose contribution was not only substantially, but also scientifically and organizationally essential for the research and published results. The lack of consistency between copyright standards for the recognition and protection of authors and guidelines provided by the codes of ethics and recommendations for scientific publications creates situations in which the authorship may be disputable. On the one hand, it may be controversial to include among the authors persons who do not contribute creatively to the copyright work creation (within the meaning of this regime) or in opposition to recognize as authors, those who only participated in the research and obtained the results included in the work. On the other hand, because of the possibility of being accused of infringing the right to authorship and committing plagiarism, the names of those have contributed creatively to the creation of the work and are co-authors according to copyright law should not be omitted.

Conclusions

Disputes about authorship in the field of scientific research and publication, allegations of plagiarism, the unreliable use and misleading indication of research are increasingly common

and medical science does not bypass them. The following guidelines can help to avoid this problem.

First of all, a distinction must be made between authorship (or co-authorship) of work as a protected copyright moral right and attributing the name of the author (or co-author) based only on their substantive or organisational involvement in conducting the research, obtaining results, or preparing publications. The rules for recognizing authorship within the meaning of intellectual property law should, in any case, prevail and should respect the actual creative participation in creating the work. Misappropriation of authorship by taking over fragments of another author's work without proper indication of who is an author, as well as the misrepresentation of a part of or the whole of someone else's work, constitutes an infringement of personal copyright in the form of plagiarism, threatened by civil liability (Article 79 of the Copyright Act) and criminal liability (Article 115 of the Copyright Act).

Secondly, ideas, discoveries, pure research data, which are not protected as such by intellectual property rights, are scientific creations protected as personal rights. The use of these kinds of intellectual achievements without identifying the persons from whom they derive does not constitute plagiarism within the meaning of copyright law, but may still be questioned as an infringement of the personal right to scientific creation under Article 23 and 24 of the Polish Civil Code.

Thirdly, to avoid infringing the principles of ethics in conducting research and scientific activities, the gap resulting from the restrictive definition of co-authors under copyright standards should be filled by identifying all the persons who participated in the research and not omitting their contribution. The researchers involved should be indicated in a different category from the authors with an appropriate annotation (e.g. "involved in research", "served as a scientific adviser", "critically reviewed a research proposal", "collected data", "provided and cared for the patients examined", "participated in the editing of publications"). Persons who contributed in this way are not entitled to authorship as a moral copyright right and do not enjoy its protection under copyright law. The omission of their names among the 'authors' does not formally constitute copyright infringement but can be targeted as an infringement of the ethical standards of scientific activity.

Fourthly, if many researchers are involved in preparing a publication, it might not be very easy afterwards to determine the contribution and authorship relevant for being recognized as an author. Therefore, the recommendation is to record all activities from the early stages, which allows the identification of the group of co-authors of the work and the persons participating in its preparation following their factual contributions, and possibly to avoid future disputes over authorship and copyright infringement.

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